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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,325

05/04/2007

Daniel Thommen

07-2352

5751

20306

7590

09/28/2009

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EXAMINER

TEMPLETON, CHRISTOPHER L

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

09/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,325	Applicant(s) THOMMEN ET AL.	
	Examiner CHRISTOPHER L. TEMPLETON	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 9-13 is/are rejected.
- 7) ☒ Claim(s) 3-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/3/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Species A: Figures 1-6

Species B: Figure 7

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-13 read on species A and claim 14 reads on species B.

The following claim is generic: Claim 1.

3. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

4. The special technical feature of species II, a compressible body, is not shared in group I. Therefore, the respective groups lack the same or corresponding special technical features and do not relate to a single general inventive concept, a posteriori, since the implant for occluding a passage in a circulatory system is not a technical feature that defines a contribution over the prior art. Freudenthal et al (WO 01/49185) discloses claim 1.

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Lack of unity of invention may be directly evident “a priori,” that is, before considering the claims in relation to any prior art, or may only become apparent “a posteriori,” that is, after taking the prior art into consideration. For example, independent claims to A+X, A+Y, X+Y can be said to lack unity a priori as there is no subject matter common to all claims. In the case of independent claims to A+X and A+Y, unity of invention is present a priori as A is common to both claims. However, if it can be established that A is known, there is lack of unity a posteriori, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

5. During a telephone conversation with Steve Courtright on 21 September 2009 a provisional election was made without traverse to prosecute the invention of species A, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claim 14 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

7. Claim 1 is objected to because of the following informalities: It appears that “reducible” is misspelled “reduceable” in claim 1.

8. Claim 7 is objected to because of the following informalities: The word “positions” in line three of the claim should be replaced with “portions”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

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9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by “the implant forming in a first state an elongated article extending along a longitudinal axis” in line 9 of the claim. For examination purposes, it was read as meaning the implant forms an elongated article (or an elongated structure), which extends along a longitudinal axis.

11. Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the occluding bodies having a compressed form in the first state within claim 10. The occluding bodies having an extended or a compressed form is not disclosed.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2, 9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Freudenthal et al (WO 01/49785).

14. As to claim 1, Freudenthal discloses an implant for occluding a passage in a circulatory system, the implant comprising a plurality of thin elongate members 2 each

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having a first end and a second end; a first holder 1 to which the first ends of the elongate members are attached; a second holder 12 (Figure 7) to which the second ends of the elongate members are attached, the elongate members being attached to the first and second holders; a first occluding body 8 (Figure 7) being attached to the elongate members. The implant forms in a first state (Figure 1) an elongated structure extending along a longitudinal axis (Figure 1), the implant being **adapted** in the first state for insertion into to the circulatory system and the implant being **adapted** to be brought into a second state in the circulatory system, wherein the distance between the holders being reducible in a manner to cause the elongate members to execute a twisting motion relative to the axis to yield a plurality of generally radially extending loops forming at least one fixation structure (Figure 7), thereby increasing a cross-section of the occluding body and the at least one fixation structure being fixable in the second state (Figure 7), and wherein the implant comprises at least one second occluding body 8 (page 14, lines 33-37) (Freudenthal discloses the occluding body 8 as being positioned on different sides of the implant) being attached to the elongate members at a distance to the first occluding body (page 14, lines 33-37) and wherein the distance between the first and the second occluding body is reducible by reducing the distance between the two holders 1, 12 (Figure 7), wherein a fixation structure (Figure 7) is formed between the first occluding body 8 and the first holder 1.

15. As to claim 2, Freudenthal discloses the first and second fixation structures as being formed in the second state (Figure 7).

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16. As to claim 9, Freudenthal discloses the implant in the second state wherein the first 8 and the second occluding body 8 have a cross-section having the same size (Figure 7 and page 14, lines 33-37) (Freudenthal discloses the occluding body 8 as being positioned on different sides of the implant). Implicitly, they would be the same size since both 6 and 7 are the same size (Figure 7).

17. As to claim 13, Freudenthal discloses the elongate members having the same length (Figures 8-9c show it the best).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freudenthal et al (WO 01/49785) in view of Solymar (U.S. Patent No. 6,488,706). Freudenthal discloses the claimed invention except for the elongate members extending through the holes of the occluding body. Solymar teaches elongate members extending through the holes of the occluding body (Figures 11-13). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the implant of Freudenthal to include the elongate members extending through the occluding body for the purpose better securing the occluding member to the elongate members.

Allowable Subject Matter

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20. Claims 3-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

21. The following is a statement of reasons for the indication of allowable subject matter: The prior art failed to disclose an occluder with two occluding bodies wherein the elongate members have a first portion arranged between the first holder and the first occluding body and a second portion arranged between the second holder and a second occluding body and a third portion arranged between the first and second occluding bodies.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Neuss et al (U.S. Patent No. 6,355,052) discloses an occluder with a plurality of elongate members and an occluding body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER L. TEMPLETON whose telephone number is (571) 270-1477. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie T. Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. L. T./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773